

## § 888.5960

to protect or support a cast. This generic type of device includes the cast heel, toe cap, cast support, and walking iron.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 888.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

[52 FR 33702, Sept. 4, 1987, as amended at 53 FR 52954, Dec. 29, 1988; 59 FR 63014, Dec. 7, 1994; 66 FR 38815, July 25, 2001]

## § 888.5960 Cast removal instrument.

(a) *Identification*. A cast removal instrument is an AC-powered, hand-held device intended to remove a cast from a patient. This generic type of device includes the electric cast cutter and cast vacuum.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 888.9.

[55 FR 48443, Nov. 20, 1990, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38816, July 25, 2001]

## § 888.5980 Manual cast application and removal instrument.

(a) *Identification*. A manual cast application and removal instrument is a nonpowered hand-held device intended to be used in applying or removing a cast. This generic type of device includes the cast knife, cast spreader, plaster saw, plaster dispenser, and casting stand.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 888.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, regarding general

## 21 CFR Ch. I (4–1–10 Edition)

requirements concerning records, and § 820.198, regarding complaint files.

[52 FR 33702, Sept. 4, 1987, as amended at 53 FR 52954, Dec. 29, 1988; 66 FR 38816, July 25, 2001]

## PART 890—PHYSICAL MEDICINE DEVICES

### Subpart A—General Provisions

Sec.

890.1 Scope.

890.3 Effective dates of requirement for premarket approval.

890.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

### Subpart B—Physical Medicine Diagnostic Devices

890.1175 Electrode cable.

890.1225 Chronaximeter.

890.1375 Diagnostic electromyograph.

890.1385 Diagnostic electromyograph needle electrode.

890.1450 Powered reflex hammer.

890.1575 Force-measuring platform.

890.1600 Intermittent pressure measurement system.

890.1615 Miniature pressure transducer.

890.1850 Diagnostic muscle stimulator.

890.1925 Isokinetic testing and evaluation system.

### Subpart C [Reserved]

### Subpart D—Physical Medicine Prosthetic Devices

890.3025 Prosthetic and orthotic accessory.

890.3075 Cane.

890.3100 Mechanical chair.

890.3110 Electric positioning chair.

890.3150 Crutch.

890.3175 Flotation cushion.

890.3410 External limb orthotic component.

890.3420 External limb prosthetic component.

890.3475 Limb orthosis.

890.3490 Truncal orthosis.

890.3500 External assembled lower limb prosthesis.

890.3520 Plinth.

890.3610 Rigid pneumatic structure orthosis.

890.3640 Arm sling.

890.3665 Congenital hip dislocation abduction splint.

890.3675 Denis Brown splint.

890.3690 Powered wheeled stretcher.

890.3700 Nonpowered communication system.

890.3710 Powered communication system.

890.3725 Powered environmental control system.